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July 2, 2008

Homeless people die after bird flu vaccine trial in Poland

Three Polish doctors and six nurses are facing criminal prosecution after a number of homeless people died following medical trials for a vaccine to the H5N1 bird-flu virus.

By Matthew Day in Warsaw
Published: 4:37PM BST 02 Jul 2008

The medical staff, from the northern town of Grudziadz, are being investigated over medical trials on as many as 350 homeless and poor people last year, which prosecutors say involved an untried vaccine to the highly-contagious virus.

Authorities claim that the alleged victims received £1-2 to be tested with what they thought was a conventional flu vaccine but, according to investigators, was actually an anti bird-flu drug.



21 people died after being given the vaccine

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The director of a Grudziadz homeless centre, Mieczyslaw Wacławski, told a Polish newspaper that last year, 21 people from his centre died, a figure well above the average of about eight.

Although authorities have yet to prove a direct link between the deaths and the activities of the medical staff, Poland's health minister, Ewa Kopacz, has said that the doctors and nurses involved should not return to their profession.

"It is in the interests of all doctors that those who are responsible for this are punished," the minister added.

Investigators are also probing the possibility that the medical staff may have also have deceived the pharmaceutical companies that commissioned the trials.

The suspects said that the all those involved knew that the trial involved an anti-H5N1 drug and willingly participated.

The news of the investigation will come as another blow to the reputation of Poland's beleaguered and poverty-stricken national health service. In 2002, a number of ambulance medics were found guilty of killing their patients for commissions from funeral companies.

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Legal immunity set for swine flu vaccine makers

Lessons of 1976 outbreak prompt early action to ward off lawsuits

AP Associated Press

updated 10:47 a.m. ET, Mon., July 20, 2009

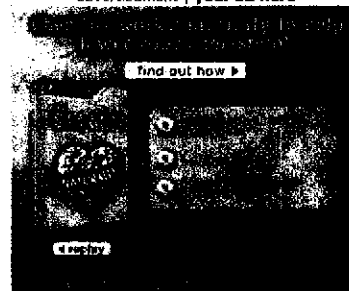
ATLANTA - The last time the government embarked on a major vaccine campaign against a new swine flu, thousands filed claims contending they suffered side effects from the shots. This time, the government has already taken steps to head that off.

Vaccine makers and federal officials will be immune from lawsuits that result from any new swine flu vaccine, under a document signed by Secretary of Health and Human Services Kathleen Sebelius, government health officials said Friday.

Since the 1980s, the government has protected vaccine makers against lawsuits over the use of childhood vaccines. Instead, a federal court handles claims and decides who will be paid from a special fund.

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The document signed by Sebelius last month grants immunity to those making a swine flu vaccine, under the provisions of a 2006 law for public health emergencies. It allows for a compensation fund, if needed.

Immunity encourages vaccine-makers

The government takes such steps to encourage drug companies to make vaccines, and it's worked. Federal officials have contracted with five manufacturers to make a swine flu vaccine. First identified in April, swine flu has so far caused at least 263 deaths, according to numbers released by the Centers for Disease Control and Prevention on Friday.

Timeline

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July 26: The CDC has announced that almost half of Americans could end up contracting the H1N1 virus within two years. Dr. Ruth Kardon of Johns Hopkins University joins MSNBC to discuss the report.

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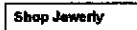
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Exhibit B
pg 1

The CDC said more than 40,000 Americans have had confirmed or probable cases, but those are people who sought health care. It's likely that more than 1 million Americans have been sickened by the flu, many with mild cases.

The virus hits younger people harder than seasonal flu, but so far hasn't been much more deadly than the strains seen every fall and winter. But health officials believe the virus could mutate to a more dangerous form, or at least contribute to a potentially heavier flu season than usual.

"We do expect there to be an increase in influenza this fall," with a bump in cases perhaps beginning earlier than normal, said Dr. Anne Schuchat, director of the CDC's National Center for Immunization and Respiratory Diseases.

On Friday, the Food and Drug Administration approved the regular winter flu vaccine, a final step before shipments to clinics and other vaccination sites could begin.

The last time the government faced a new swine flu virus was in 1976. Cases of swine flu in soldiers at Fort Dix, N.J., including one death, made health officials worried they might be facing a deadly pandemic like the one that killed millions around the world in 1918 and 1919.

Thousands filed claims after 1976 campaign

Federal officials vaccinated 40 million Americans during a national campaign. A pandemic never materialized, but thousands who got the shots filed injury claims, saying they suffered a paralyzing condition called Guillain-Barre Syndrome or other side effects.

"The government paid out quite a bit of money," said Stephen Sugarman, a law professor who specializes in product liability at the University of California at Berkeley.

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Vaccines aren't as profitable as other drugs for manufacturers, and without protection against lawsuits "they're saying, 'Do we need this?'" Sugarman said.

The move to protect makers of a swine flu didn't go over well with Paul Pennock, a prominent New York plaintiffs attorney on medical liability cases. The government will likely call on millions of Americans to get the vaccinations to prevent the disease from spreading, he noted.

"If you're going to ask people to do this for the common good, then let's make sure for the common good that these people will be taken care of if something goes wrong," Pennock said.

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Most parents in favor of school swine flu shots

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Exhibit B
pg 3

Official CDC website

July 27, 2009

**Centers for Disease Control and Prevention**
QUESTIONS & ANSWERS**Thimerosal in Seasonal Influenza Vaccine****What is thimerosal?**

Thimerosal is a very effective preservative that has been used since the 1930s to prevent contamination in some multi-dose vials of vaccines (preservatives are not required for vaccines in single dose vials). Thimerosal contains approximately 49% ethylmercury. There is no convincing evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site. However, in July 1999 the Public Health Service (PHS) agencies, the American Academy of Pediatrics (AAP), and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure.

Today, all routinely recommended licensed pediatric vaccines that are currently being manufactured for the U.S. market, with the exception of influenza vaccine, contain no thimerosal or only trace amounts. Thimerosal preservative-free influenza vaccines are available, but in limited quantities. The total amount of inactivated influenza vaccine available without thimerosal as a preservative will continue to increase as manufacturing capabilities are expanded.

Does the influenza vaccine contain thimerosal?

Yes, the majority of influenza vaccines distributed in the United States currently contain thimerosal as a preservative. However, some contain only trace amounts of thimerosal and are considered by the Food and Drug Administration (FDA) to be preservative-free. Manufacturers of preservative-free flu vaccine use thimerosal early in the manufacturing process. The thimerosal gets diluted as the vaccine goes through the steps in processing. By the end of the manufacturing process there is not enough thimerosal left in the vaccine to act as a preservative and the vaccine is labeled "preservative-free".

How much thimerosal-free influenza vaccine is expected to be available for the 2008-09 season?

For the 2008-09 season, manufacturers project producing as many as 50 million doses of thimerosal-free or preservative-free (trace thimerosal) influenza vaccine. Of these 50 million doses, approximately 20 million doses represent flu vaccine products that are licensed for use in children over 3 years of age.

Will the supply of thimerosal-free and preservative-free (trace thimerosal) influenza vaccine be adequate for the recommended pediatric priority groups (ages 6-59 months) during the 2008-09 season?

For the 2008-09 season, there is one product licensed for 6-23 month old children (the product is thimerosal-free). For children between the ages of 2 and 5 years of age, there are three products available that are thimerosal-free (sanofi's Fluzone; MedImmune's FluMist) or preservative-free (trace thimerosal- [Novartis's Fluvirin]). Specific information about these products and other influenza vaccines can be found in the [Table: Influenza Vaccine Manufacturers for the 2008-09 Influenza Season](http://wwwdev.cdc.gov/flu/about/qa/vaxsupply.htm#table) (<http://wwwdev.cdc.gov/flu/about/qa/vaxsupply.htm#table>). Given the uptake of influenza vaccine among children less than 5 years of age, and the anticipated increase in vaccination coverage for this season, CDC projects that the vaccine supply for this age group will be adequate to meet demand.

Exhibit C
Pg 1

Official CDC website

Is it safe for children to receive an influenza vaccine that contains thimerosal?

Yes. There is no convincing evidence of harm caused by the small amount of thimerosal in vaccines, except for minor effects like swelling and redness at the injection site due to sensitivity to thimerosal. Most importantly, since 1999, newly formulated thimerosal preservative-free childhood vaccines (Hepatitis B, Hib, and DTaP) have been licensed. With the newly formulated childhood vaccines, the maximum total exposure during the first six months of life will now be less than three micrograms of mercury. Based on guidelines established by the FDA, the Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR), no child will receive excessive mercury from childhood vaccines regardless of whether or not their flu shot contains thimerosal as a preservative.

Research suggests that healthy children under the age of 2 are more likely than older children and as likely as people over the age of 65 to be hospitalized with flu complications. In addition, children between 24-59 months of age have higher rates of influenza-related doctor and Emergency Department visits than older children. Therefore, vaccination with either reduced or standard thimerosal-content flu vaccine is recommended for children between the ages of 6 and 59 months by CDC's Advisory Committee on Immunization Practices.

Is it safe for pregnant women to receive an influenza vaccine that contains thimerosal?

Yes. A study of influenza vaccination examining over 2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine. Case reports and limited studies indicate that pregnancy can increase the risk for serious medical complications of influenza. One study found that out of every 10,000 women in their third trimester of pregnancy during an average flu season, 25 will be hospitalized for flu related complications.

Additionally, influenza-associated excess deaths among pregnant women have been documented during influenza pandemics. Because pregnant women are at increased risk for influenza-related complications and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefits of influenza vaccine with reduced or standard thimerosal content outweighs the theoretical risk, if any, of thimerosal.

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Exhibit C
pg 2

Neuzil KM, Reed GW, Mitchel EF, Simonsen L, Griffin MR. Impact of influenza on acute cardiopulmonary hospitalizations in pregnant women. *Am J of Epidemiol* 1998;148(11):1094-102.

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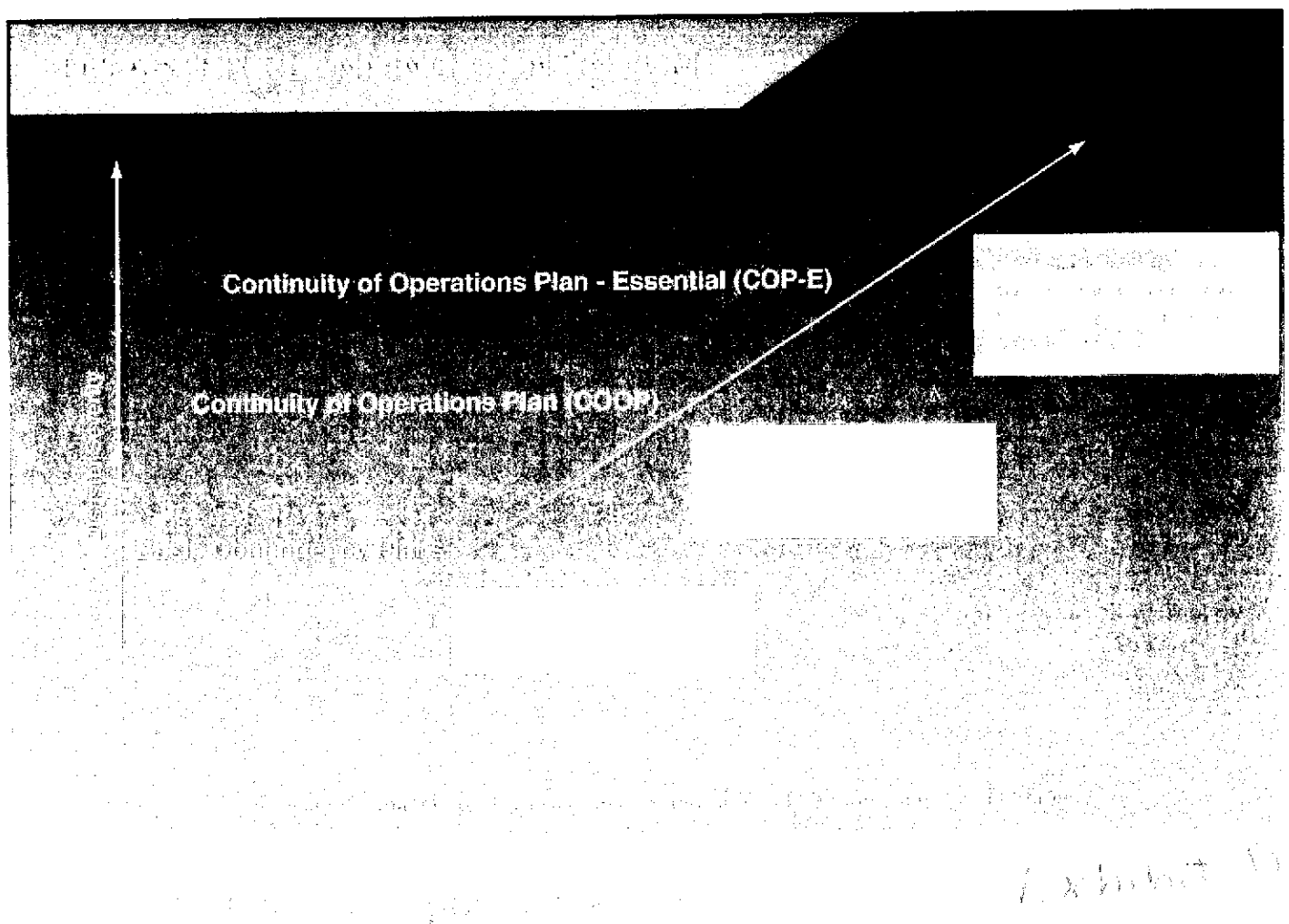
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Exhibit C
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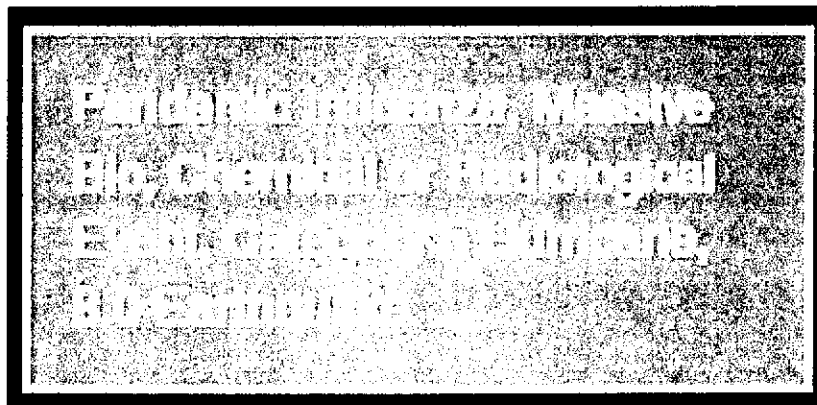
5.2 How Does COP-E Fit with Current Contingency Plans?

COP-E is an extension and refinement of current business contingency and continuity of operations planning that fully exploits existing efforts and integrates within the suite of business disaster plans. The COP-E process assumes severe pandemic-specific impacts to enhance and compliment existing business continuity plans. In addition, COP-E integrates the additional actions needed to identify and prioritize essential functions, people, and material within the business, across business sectors, and as important for the community and the nation. It highlights actions and options to protect and sustain these at each pandemic phase from preparation to recovery. In addition, COP-E incorporates a measured approach for "survival" under distinct COP-E scenarios, and serves a broader mission as an enhancement process for business continuity planning to address other catastrophic disasters like an extreme biological, chemical or radiological attack. Each COP-E scenario will be highlighted in the following sections.



- **Basic Contingency Planning:** To some degree, all business types and sizes should already have contingency plans to prepare for and respond to business disruptions, such as localized power outages, snow storms, plant fires, IT failures, and myriad other possibilities.
- **Continuity of Operations Plan (COOP):** Many businesses, particularly large ones, produce formal business continuity plans to address potentially significant business disruptions based on an assessment of their

Close up view of the box showing what enables the Continuity of Operations Plan - Essential (COP-E) in the defendant's "Disaster Planning Continuum chart" located on pg 29 of the training booklet PANDEMIC INFLUENZA Preparedness, Response and Recovery, which is published by the defendant.



As we can see in the above box, the defendant considers an earthquake measuring 8.0 on the Richter scale to be in the same category as a Pandemic Influenza, a term so loosely defined that the World Health Organization already deemed America to be in a Phase 6 influenza pandemic, even though the WHO admits a small number of people are infected by it. The record shows the largest amount of flu virus to expose people was when the WHO had 72 kilos of virus transported on a passenger train in Lausanne, Switzerland. Police records show dry ice packing the virus exploded, releasing the virus on the train.

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W.H.O. Says It Plans to Stop Tracking Swine Flu Cases

By DONALD G. McNEIL Jr.
Published: July 16, 2009

In a move that caught many public health experts by surprise, the World Health Organization quietly announced Thursday that it would stop tracking swine flu cases and deaths around the world.

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The announcement, made in a "briefing note" posted on the organization's Web site late in the day, perplexed some experts, and even baffled a W.H.O. spokesman, Gregory Hartl, who

said in an e-mail message, "I don't have reliable info" about what his agency would track instead.

Only a little earlier in the day, Mr. Hartl had confirmed that Argentina, with 137 swine flu deaths since June, had surpassed Mexico, where the epidemic began in February, as the country with the second-largest number of swine flu deaths. Mexico has 121; the United States, with a much larger population, has 211.

The last W.H.O. update, issued July 6, showed 94,512 confirmed cases in 122 countries, with 429 deaths.

Many epidemiologists have pointed out that, in reality, millions of people have had swine flu, usually in mild form, so the numbers of laboratory-confirmed cases were actually meaningless. And performing the tests has overwhelmed many national laboratories.

But the cases — and, more to the point, the deaths — have been closely watched by the media and flu experts, even those who knew they were undercounts, as a crude measure of how the epidemic spread around the globe. Such figures can also, in theory, be useful to public health officials. For example, knowing that Chile has had far fewer deaths than Argentina even though their outbreaks began almost simultaneously could be useful to other

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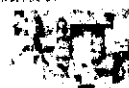
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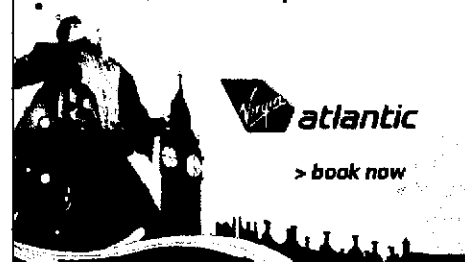


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Exhibit F
pg 1

countries who might want to imitate Chile's response.

The briefing note said countries would still be asked to report their first few confirmed cases. It also said countries should watch for clusters of fatalities, which could indicate the virus had mutated to a more lethal form. Other "signals to be vigilant for," it said, were spikes in school absenteeism and surges in hospital visits.

Wealthy countries routinely collect such data, and also do blood tests to see what percentage of a population has flu antibodies, indicating they were infected but recovered. However, poor countries do not.

Dr. Joseph S. Bresee, chief of epidemiology for the C.D.C.'s flu division, said he agreed with the W.H.O. premise that case counts were just too inaccurate to keep using.

"I don't know exactly what their plans are," he said, adding that he hoped they would track the severity and spread of flu cases over time, as his agency does state-by-state in flu season. "But it's not like they're just going to let the screen go blank."

Dr. Michael T. Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota, said confused journalists in many countries had misread the low W.H.O. numbers of confirmed deaths to report that the new flu is not a threat. And testing is so hit-or-miss that even apparent differences in death rates like those between Chile and Argentina "may not be based in science," he said.

"Bad measures can be worse than no measures at all," he added. "But I hope this will force the public health community to come up with better ones."

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A version of this article appeared in print on July 17, 2009, on page A9 of the New York edition.

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VIRUS ALARM IN SWITZERLAND

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Swine Flu Container Explodes on Train

When a container holding swine flu exploded on a Swiss train on Monday, it could have led to a nightmare scenario. Luckily the virus was not the mutated swine flu that has killed around 150 people in Mexico and that has already spread to parts of Europe.

It has all the hallmarks of a disaster movie: A container filled with the swine flu virus explodes on a busy train. But that's exactly the scenario that briefly caused the Swiss authorities some alarm on Monday evening. In the midst of global fears of a swine flu pandemic, a container with swine flu exploded on a train carrying over 60 people.



The Intercity train is seen in Lausanne station after it had been evacuated.

Luckily, however, it was not the mutated swine flu virus that has killed around 150 people in Mexico. The police quickly reassured the public that there was no danger of any infection.

According to the police, a lab technician with the Swiss National Center for Influenza in Geneva had travelled to Zurich to collect eight ampoules, five of which were filled with the H1N1 swine flu virus. The samples were to be used to

develop a test for swine flu infections.

The containers were hermetically sealed and cooled with dry ice. However, it seems the dry ice was not packed correctly and it melted during the journey. The gas coming from the containers then built up too much pressure and the ampoules exploded, as the train was pulling into a station.

After consulting with a virologist, the police stopped the train just before Lausanne station and evacuated it, taking the precaution to isolate all those on board for one hour. A specialist for infectious diseases then reassured all those involved that the particular strain of swine flu on the train posed no risk for humans.

Taking no chances, the police took the contact details of all the passengers before allowing them to continue on their journey.

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